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Office of Regulatory Policy
HFD - 13
5600 Fishers Lane,
Rockville, MD 20857

Attention: Claudia Grillo

Dear Ms. Axelrad:

Transmitted herewith is a copy of the application for patent term extension of U.S. Patent No. 4,840,896. The application was filed on November 20, 2000, under 35 U.S.C. § 156.

The patent claims a product that was subject to regulatory review under the Federal Food, Drug and Cosmetic Act. Subject to final review, the subject patent is considered to be eligible for patent term restoration. Thus, a determination by your office of the applicable regulatory review period is necessary. Accordingly, notice and a copy of the application are provided pursuant to 35 U.S.C. § 156(d)(2)(A).

Inquiries regarding this communication should be directed to Kathleen Kahler Fonda at (571) 272-7754 (telephone) or (571) 273-7754 (facsimile).

Kathleen Kahler Fonda for
Karin Ferriter
Patent Attorney
Office of International Relations

cc: Roger L. Browdy
Browdy and Neimark PLLC
624 Ninth Street NW
Suite 300
Washington DC 20001-5303

RE: choriogonadotropin alfa (recombinant human chorionic gonadotropin (r-HCG)
Docket No. REDDY=2EXT